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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,384	10/20/2003	Curtis Wright IV	6750-237-99	2381

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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
03/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,384	WRIGHT, CURTIS	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 23-44* is/are pending in the application.

4a) Of the above claim(s) *24 and 29-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19, 23, 26, 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 4, 2010 has been entered.

Claims 1-19, 23-25, 27-44 remain pending in this application. Claims 24, 27, and 29-44 remain withdrawn from consideration.

Withdrawn Rejections/Objections

Claim Objections

The objection to claim 10 because of the following informalities: It appears Applicant has misspelled octoanol has been withdrawn in view of Applicants amendment to the claim to correct the spelling.

Claim Rejections - 35 USC § 103

The rejection of claims 1-19 and 23 under 35 U.S.C. 103(a) as being unpatentable over Kwiatek et al. (US Patent 4,573, 996) in view of Pagades et al. (US Patent 6,221,384) has been withdrawn in view of Applicants arguments regarding the lack of a teaching of a drug in matrix formulation within the transdermal device.

The rejection of claims 25-26, and 28 under 35 U.S.C. 103(a) as being unpatentable over Pagedas (US Patent 6,221,384) in view of Cleary et al. (US Patent 5,006,342) has been withdrawn in view of Applicants amendment to claim 25 to recite an impermeable layer on the surface of the backing layer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-19, 23, 25, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blitzer et al. (US Patent 6,475,514) in view of Reder et al. (US Patent 6,344,212) and further in view of Pagedas (US Patent 6,221,384).

Blitzer discloses an athletic patch for the administration of athletic supplement nutrients. The patch is preferably a transdermal patch which includes an athletic supplement reservoir which may optionally include a permeation enhancer and/or a matrix, an impermeable backing layer, on one side of the athletic supplement reservoir and an adhesive overlay which forms a boundary on the other side of the athletic supplement reservoir (column 9, lines 1-8).

When the patch is a transdermal patch, it is applied to the surface of the skin by a contact adhesive e layer (column 9, lines 55-57). The adhesive layer may be a single continuous layer across the entire surface of the transdermal patch or it may cover the

perimeter edges of the patch but not on the area from which the athletic supplement is released (column 10, lines 60-64).

The athletic supplement may be incorporated into a matrix such as gels, natural and synthetic rubbers and other polymeric materials, mineral oil and petroleum jelly (column 11, lines 28-32).

The backing layer is impermeable and defines the top of the transdermal delivery patch. The backing is occlusive because it prevents loss of the athletic supplement and/or enhancers to the environment. The backing layer may be prepared from any material which is impermeable to the athletic supplement and other components of the patch. It may be a single layer or may be composed of several different types of layers (column 11, lines 45-55), thereby meeting the limitation of an impermeable layer and a backing layer.

Generally the transdermal patch includes a liner which is positioned adjacent to the surface of the adhesive layer and which is removed prior to application of the transdermal patch to the skin. The liner which is used to cover the adhesive backing during storage and to prevent an evaporative loss of the athletic supplement during storage may be made from any impermeable film (column 12, lines 15-20).

Preferred embodiments disclose the drug matrix comprises 0.1-20% by weight of the athletic supplement however, this can be adjusted based on the actual substance used. Therefore, it is the position of the Examiner that based on the drug used; the skilled artisan would be readily able to determine the drug load based on the bioavailabilty and the permeation of the drug through the skin.

The patches can be stored in pouches (column 12, lines 27-28).

Blitzer does not disclose the administration of buprenorphine and Blitzer does not disclose a plurality of patches which are separated prior to application.

Reder discloses the transdermal administration of buprenorphine (abstract). Reder additionally discloses the softening agents including dodecanol, undecanol and octanol, as well as esters of carboxylic acids can be used in conjunction with the burprenorphine (column 20, lines 1-3).

Blitzer discloses his device is useful for avoiding gastrointestinal metabolism, reduces first pass effects, and may provide a longer course of release (column 2, lines 18-28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the buprenorphine of Reder into the device of Blitzer since Reder discloses it is suitable for use in transdermal devices and it's a potent, partial agonist opioid analgesic with desirable therapeutic properties. It is 50-100 times more potent than morphine (column 1, lines 51-64).

Pagedas teaches a transdermal segmented dosage unit for administering a dosage of a pharmaceutical to the skin of a patient with means for dividing and severing the dosage unit into pre-selected segmental areas corresponding to fractional dosages of pharmaceutical. The fractional dosages may be administered in any pre-selected combination (abstract).

Regarding claims 12-19, Pagedas's transdermal dosage unit, discloses, "a series of perforations or alternately, scoring lines, with purpose to divide the dosage unit into a

series of dose specific segments. Thus the dosage unit patch may be used in its entirety for the full dosage, or in the alternative, may be separated along perforate or scored lines to reduce the dosage received by a predetermined amount" (column 1, lines 50-55). It is the examiners position that the skilled artisan would also be able to manufacture the patches in whatever size, shape, and amount of units desired. It would also be within the knowledge of the skilled artisan to package the patches in any way deemed appropriate including reseal able packages. Applicant's attention is directed to Pagedas's drawings for a clear representation of the dosage units. Applicants attention is also directed to MPEP 2144.04 IV, in which the court held that changes to dimensions where the dimensions would not perform differently are not patentably distinct over the prior art. Furthermore the recitation of packaging components in which the transdermal patch are stored, do not provide a patentable distinction between the prior art patch and the instant patch since the packaging do not change the performance characteristics and thus a material effect on the method of using/treatment.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the geometry of Blitzer's device to prepare segmented dosage units as taught by Pagedas in order to provide the appropriate dosage of the drugs to be administered as taught by Pagedas thereby eliminating waste and cost to the patient.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blitzer et al. (US Patent 6,475,514) in view of Reder et al. (US Patent 6,344,212) and Pagedas (US Patent 6,221,384) and further in view of Royds et al. (US Patent 5,667,798).

The combination of Blitzer, Reder and Pagedas is discussed above and applied in the same manner.

The combination does not disclose the active agent being encapsulated in microcapsules.

Royds discloses a transdermal drug delivery device in which the drug is microencapsulated with a matrix of gums and gelling agents (column 1, line 68 through column 2, line 2). Royds additionally discloses the release is subject to the material used for preparing the coating material (column 2, lines 4-6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have encapsulated the active agent of the drug in the matrix of the transdermal patch of Blitzer in order to provide a controlled release of the active agent from the transdermal device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615